



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0823]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

**DATES:** Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF**

**PUBLICATION IN THE *FEDERAL REGISTER***]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2013-N-0823 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Format and Content Requirements for Over-the-Counter Drug Product Labeling--21 CFR Part 201

OMB Control Number 0910-0340--Extension

This information collection supports FDA regulations at § 201.66 (21 CFR 201.66), which establish standardized content and format requirements for the labeling of all marketed OTC drug products. The regulations set forth the content and format requirements for the Drug Facts portion of labels on OTC drug products. These regulations require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features.

Currently marketed OTC drug products are already required to comply with these labeling requirements and will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Labeling modifications already required to be in Drug Facts format are "usual and customary" as part of routine redesign practice, thus they do not create additional burden within the meaning of the PRA.

Therefore, burden for this information collection is that which is necessary to comply with the labeling requirements in § 201.66, applicable to new OTC drug products and OTC sunscreen drug products introduced to the marketplace under new drug applications, abbreviated

new drug applications, or an OTC drug monograph. New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on our electronic drug registration and listing database, we estimate that approximately 10,463 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimate that these SKUs are marketed by 1,416 manufacturers. We estimate that the preparation of labeling for new OTC drug products requires 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is 94,296 hours.

All currently marketed sunscreen products are required to comply with the Drug Facts labeling requirements in § 201.66, so they will incur no further burden under the information collection provisions in the regulation. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate, based on our electronic drug registration and listing database, that 5,253 new SKUs of OTC sunscreen drug products will be marketed each year. We estimate that these 5,253 SKUs will be marketed by 294 manufacturers. We estimate that 12 hours will be spent on each label. This is reflected in table 1, row 1.

When determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). We receive very few requests for exemptions or deferrals. We also estimate that a request for deferral or exemption requires 24 hours to complete. This is reflected in table 1, row 2.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
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§ 201.66(c) and (d) for new OTC drug products	855	9.19	7,858	12	94,296
§ 201.66(e)	1	1	1	24	24
Total					94,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 82,797 hours and a corresponding increase of 6,898 disclosures. This increase corresponds with data obtained from our database.

Dated: June 14, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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